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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,289	10/25/1999	John Luke Toner	REF/TONER/19	9341

7590

04/10/2003

ROYAL N. JR., VICE PRESIDENT
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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/10/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/425,289

Applicant(s)

TONER ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 8-38 is/are pending in the application.
- 4a) Of the above claim(s) 8-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/04/2003 has been entered.

Response to Amendment

Claims 1-3, 7, 39 and 40 have been canceled. Claims 5 and 38 have been amended. Consequently, since claims 8-37 are withdrawn, claims 4-6 and 38 have been examined herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuru (US Pat. 5,055,307).

Tsuru discloses a method of embolus therapy (i.e., vascular embolization treatment, see column 3, lines 27-30 and column 4, lines 40) comprising administering a composition comprising particles of hydroxyapatite having a size of 5 to 1000 um. The method further includes diagnostic imaging of the particles, see abstract and column 5, lines 36+. The particles are porous particles of hydroxyapatite which encapsulate an X-ray contrast medium, sodium iothalamate, see example 1. The particles or granules of the hydroxyapatite in example 1 are the same as the particles claimed and exemplified in the present application (i.e., example 14, page 34). Also the embolic particles disclosed by Tsuru are prepared by a method which is the same as set forth in the instant application, i.e., hydroxyapatite particles are prepared (note, these particles are porous) and the particles are mixed with a solution of a

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water soluble x-ray contrast agent (e.g., iohexol, as in example 14 of the application, and sodium iothalamate in the prior art, see example 1 of Tsuru), so that the contrast agent enters the pores of the hydroxyapatite particles and is encapsulated therein. Thus, the particles disclosed by Tsuru are the same as the particles being claimed. Also, Tsuru discloses a method of embolus therapy with subsequent imaging using said particles, as set forth above. The limitation of claim 4 is an inherent property of an embolization method, as this is the desired effect of embolization.

Response to Arguments

Applicant's arguments filed 3/4/2003 have been considered but are not found persuasive.

Applicant asserts that Tsuru discloses methods which use particles which may be coated with a soluble organic polymeric coating, while the present invention claims the use of particles encapsulated by a non-polymeric coating.

This is not found persuasive for two reasons. Firstly, the claims do not exclude such a coating. The claims only require that the matrix is non-polymeric (e.g., hydroxyapatite, as defined by claim 6), and Tsuru discloses the same matrix which encapsulates (in the pores) and x-ray contrast agent. Note: while the claim recite that the particles are "consisting essentially of" for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. Secondly, Tsuru does not require the use of a coating, as Tsuru clearly discloses that such an organic coating is optional, see columns 3-4. Disclosed examples and preferred embodiments do not constitute a teaching which is away from a broader disclosure. *In re Susi*, 169 USPQ 423 (CCPA 1971). Thus, since 1) the coating disclosed by Tsuru is optional and 2) the claims do not clearly indicate that a coating is excluded, this argument is not found persuasive. Further, Tsuru clearly discloses both a method of embolism and imaging, by stating embolic therapy as a use and a desire to use particles which are detectable by imaging, but adding an x-ray contrast agent.

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C nclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
April 8, 2003